

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

DILORENZO BIOMEDICAL, LLC,

Plaintiff,

v.

LIVANOVA, INC., and LIVANOVA
USA, INC.,

Defendants.

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Civil Action No. 4:23-cv-1800

Patent Case
Jury Trial Demanded



**DILORENZO BIOMEDICAL'S OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS PURSUANT TO
FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) AND 12(b)(7)**

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INTRODUCTION

Plaintiff DiLorenzo Biomedical, LLC (“DBM”) holds an exclusive license from a predecessor of Defendants LivaNova, Inc. and LivaNova USA, Inc. (together referred to as “LivaNova”) with respect to two of the three patents asserted in this case under an “Agreement” that LivaNova has identified as Ex. E.¹ LivaNova claims that because the exclusive license is limited to a specified field of use, it had to be joined as a co-plaintiff in order for a suit by the licensee to go forward. Under long-established precedent, however, this objection does not hold where, as here, the party accused of infringement is also the patent owner and is already present as a defendant and thus situated adequately to protect its own interests.

LivaNova also contests the scope of exclusivity, asserting that it does not cover the “sympathetic nervous system modulation therapy” that DBM sues about. DBM’s exclusive rights under the Agreement extend to a “Field of Use” “for sympathetic nervous system modulation therapy and for neuromodulation therapy for treating obesity and other metabolic disorders.” The Field of Use reads as comprising (i) sympathetic nervous system modulation therapy and (ii) neuromodulation therapy for treating obesity and other metabolic disorders. LivaNova erroneously asserts that the entire grant is nevertheless limited to “treating obesity and other metabolic disorders.” For this, it relies on (A) an earlier agreement to negotiate (as opposed to the words of the later agreement actually reached) and (B) extrinsic documents that LivaNova misreads, which are in fact contrary to LivaNova’s position. Moreover, further documents LivaNova did not submit, including the sequence of drafts of the Agreement itself, as well as other correspondence with LivaNova’s predecessors-in-interest, undercut LivaNova’s theories.

Furthermore, there is a *third* patent in the case, which is owned outright by DBM, as to

¹ References to Exs. A–N herein are to those Exs. A–N LivaNova attached to its Motion.

which LivaNova overlooks other material terms of the Agreement. In sum, this is not a meritorious dispositive motion.

NATURE AND STAGE OF THE PROCEEDINGS

DBM filed its Complaint for patent infringement (Dkt. No. 1) on May 17, 2023.

LivaNova filed its Motion to Dismiss (Dkt. No. 21) on October 16, 2023.

STATEMENT OF THE ISSUES TO BE RULED UPON BY THE COURT

1. Does DBM, as a licensee of two of the three patents-in-suit, lack standing to sue on those patents without having joined LivaNova as a co-plaintiff?

Response: No, DBM has both Art. III and prudential standing without the necessity to join LivaNova as a co-plaintiff.

2. Is DBM's exclusively granted Field of Use as to sympathetic nervous system modulation therapy limited only to treatment of obesity and other metabolic disorders?

Response: No, by ordinary grammatical and applicable contract interpretation principles, the words "for treating obesity and other metabolic disorders" do not limit the preceding grant provision, "for sympathetic nervous system modulation therapy." The extrinsic evidence only confirms this.

3. Is DBM the owner of the '880 patent?

Response: Yes. The '880 patent is owned of record by DBM, and DBM duly complied with any obligations it had to LivaNova's predecessor-in-interest that would otherwise have affected ownership of that patent.

SUMMARY OF THE ARGUMENT

DBM has both Art. III and prudential standing to sue LivaNova, for LivaNova's own infringement of the licensed patents within the scope of the exclusive license to DBM. Because it holds an exclusive license, DBM suffers actual injury from the conduct alleged, representing a justiciable case or controversy under Art. III. Because LivaNova's presence in the case as a defendant provides an adequate basis for LivaNova to protect its own interests in the matter, and because LivaNova cannot sue itself, DBM has prudential standing as well.

It is clear from the grant language itself that DBM's Field of Use of sympathetic nervous system modulation therapy is not limited to treating obesity and other metabolic disorders. LivaNova fails to cite objective evidence concerning the formation of the Agreement that establishes a contrary intent, or evidence confirming any later understanding to the contrary.

Moreover, to the extent extrinsic evidence is considered, there is also substantial written evidence, which LivaNova fails to address, reflecting that DBM specifically brought to LivaNova's predecessor's attention that DBM was applying for and intended to own patents with claims concerning sympathetic nervous system modulation, solicited the predecessor's views with regard to these being within DBM's Field of Use, and that the predecessor confirmed it would consider the issue, and raised no objection. This record is completely inconsistent with LivaNova's theories herein.

DBM further has standing to bring claims of infringement of the '880 patent against LivaNova because DBM is the owner of the '880 patent. There were contractual provisions obligating its principal, Dr. Daniel J. DiLorenzo, to disclose such inventions to NeuroBionics Corporation ("NeuroBionics," which was later renamed BioNeuronics Corporation ("BioNeuronics")), with which he complied. He also notified BioNeuronics of his patent applications within the Field of Use, disclosing the applications themselves, and carried the cost of patent prosecution and maintenance—leaving no basis for LivaNova years later to claim any ownership interest whatsoever in the '880 patent.

BACKGROUND

A. Patents-in-suit

DBM is the exclusive licensee of U.S. Pat. Nos. 6,366,813 (the "'813 patent") and 7,209,787 (the "'787 patent") under an exclusive license granted by LivaNova's predecessor-in-interest. DBM owns of the third patent in suit, U.S. Pat. No. 9,345,880 (the "'880 patent").

B. Relevant technical background

The patents-in-suit relate generally to neuromodulation, which is the delivery of a stimulus to the nervous system.² The relevant hierarchy of the nervous system is that it comprises the central nervous system (brain, spinal cord) and the peripheral nervous system. *See Organization of the Nervous System*, NAT'L CANCER INST., <https://training.seer.cancer.gov/anatomy/nervous/organization/> (Abramson Decl., Ex. 2). The peripheral nervous system subdivided into an afferent (sensory) division and an efferent (motor) division. *Id.* The efferent (motor) division is again subdivided into the somatic nervous system and the autonomic nervous system. *Id.* The autonomic nervous system is further subdivided into the sympathetic nervous system and the parasympathetic nervous system. *Id.*

C. The exclusive license agreement between DBM and LivaNova's predecessor-in-interest

On June 25, 1999, Dr. DiLorenzo filed a patent application relating to closed-loop neuromodulation, which issued as the '813 patent.³ Dkt. No. 1-1 at 1. On November 20, 2003, he filed a further application claiming priority to the '813 patent, which issued as the '787 patent. Dkt. No. 1-2 at 1.

LivaNova's interests involve a succession of entities beginning with NeuroBionics, which LivaNova ultimately acquired. Dr. DiLorenzo founded NeuroBionics in November 2002 and later executed a Founder Agreement, dated March 31, 2004 (Ex. A).⁴ Dr. DiLorenzo assigned a set of patents, including the '813 patent and later patent applications claiming priority thereto

² *See* <https://www.neuromodulation.com/neuromodulation-defined> (attached as Ex. 1 to the Declaration of Ronald Abramson, dated November 6, 2023 ("Abramson Decl.")).

³ In its Motion, LivaNova incorrectly refers to the '813 patent family as "relating to epilepsy treatment." Mot. at 14. The scope of the patents' claims is by no means so limited.

⁴ *See* Declaration of Daniel J. DiLorenzo ¶ 2, dated November 6, 2023 ("DiLorenzo Decl.").

(the “Licensed Patents”) to NeuroBionics. Ex. A ¶ 2(a), Schedule I. The Founder Agreement provided that Dr. DiLorenzo would execute a “Non-Disclosure and Developments Agreement,” in a form attached. *Id.* ¶ 14 (emphasis in original). That agreement excluded certain developments from the obligation to assign, including those relating to “Autonomic Modulation and Neuromodulation for Obesity & Metabolism.”⁵ Ex. A, Schedule III ¶ 4(b), Appendix.

On December 14, 2004, in connection with [REDACTED], Dr. DiLorenzo and NeuroBionics amended the Founder Agreement (Ex. B) and executed a formal assignment agreement (Ex. C). Around this time, the parties were also negotiating what rights in the Licensed Patents that Dr. DiLorenzo would retain. DiLorenzo Decl. ¶ 2. However, because the parties were unable to resolve these issues by the time of the execution of the December 14, 2004 documents, the parties memorialized an intent to “use best efforts” to come to terms in the future. *See* Agreement at 2; Ex. C at 1.

A draft of a license agreement, dated January 25, 2005 (DiLorenzo Decl., Ex. 1), incorporated an exclusive license of the Licensed Patents by NeuroBionics in favor of Dr. DiLorenzo’s newly formed company, DBM,⁶ which would have been limited to a Field of Use defined as:

Neuromodulation for Obesity and Metabolism and Modulation of the
Sympathetic [sic] Nervous System

Id. ¶ 3, Ex. 1 at. 1 (emphasis added). This definition shows that the Field of Use would have two separate and distinct branches: (1) neuromodulation for obesity and metabolism and (2)

⁵ This exclusion was later incorporated into the Proprietary Information, Inventions Agreement and Noncompete Agreement executed on February 8, 2005. *See* Ex. D ¶ 4(c).

⁶ There have been two companies named DiLorenzo Biomedical, LLC. The first, formed April 24, 2005, was administratively dissolved on September 2, 2014. Its property was assigned in dissolution to Dr. DiLorenzo who assigned such property on March 23, 2021 to the second so-named corporation formed March 3, 2021 (Plaintiff herein).

modulation of the sympathetic nervous system.

A later draft from on or around March 2005 (*id.*, Ex. 2) shows that the parties had made significant changes to the definition of the Field of Use. In particular, this draft shows Dr. DiLorenzo's edits to the definition in tracked changes. The definition of the Field of Use prior to Dr. DiLorenzo's edits is shown below:

devices and methods for neuromodulation therapy and sympathetic nervous system modulation therapy for treating obesity and other metabolism disorders

Id. at 1. This definition appears to have jumbled the words of the prior draft. The "obesity" modifier no longer followed "neuromodulation" but rather "sympathetic nervous system modulation [therapy]."

Dr. DiLorenzo's edits to the Field of Use are shown in tracked changes below:

devices and methods for sympathetic nervous system modulation therapy and
for neuromodulation therapy ~~and sympathetic nervous system modulation therapy~~
for treating obesity and other metabolic ~~csn~~ disorders

Id. This revision corrected the error in the previous version and associated the broader "neuromodulation therapy" with the "obesity" modifier. *Id.* ¶ 5. Further, in order to avoid any confusion that "sympathetic nervous system modulation therapy" would also be modified by the "obesity" phrase, Dr. DiLorenzo inserted an additional "for" so that both branches of the Field of Use were parallel in their introduction by the word "for." *Id.*

Dr. DiLorenzo's changes were incorporated into the final Agreement, which was executed on May 23, 2005 by DBM and NeuroBionics (by then, BioNeuronics). Agreement ¶ 4. Under the Agreement (and in accordance with Dr. DiLorenzo's edits referenced above), BioNeuronics granted DBM a "perpetual, fully paid up, worldwide, exclusive license" to the Licensed Patents (with rights to sublicense) in a field of use comprising,

devices and methods for sympathetic nervous system modulation therapy and
for neuromodulation therapy for treating obesity and other metabolic disorders

Agreement ¶ 4 (the “Field of Use”).

The Agreement further addressed new IP in the Field of Use. Under a series of agreements going back to March 2004, Dr. DiLorenzo was obligated to disclose his inventions to the company. When the Agreement was later executed on May 23, 2005, ¶ 6 thereof provided that DBM would solely own any future patent application “claim[ing] priority to one of more of the Licensed Patents and claim[ing] exclusively an invention within the [Exclusive] Field of Use.” *Id.* ¶ 6. This provision further stated that “[DBM] shall be responsible for all costs of filing and prosecution of the patent application and subsequent maintenance of the patent issuing from such patent application.” *Id.*

DBM and BioNeuronics further included in the Agreement the procedure by which they could sue for infringement of the Licensed Patents by third parties. *Id.* ¶ 10. This provision addresses events where (1) both DBM and BioNeuronics wanted to sue, (2) the parties did not agree but BioNeuronics wanted to sue, or (3) (absent either of the foregoing) DBM nevertheless wanted to sue the third party, in which case it could institute the suit, including, if required “for standing purposes,” joining BioNeuronics as a party (*id.*).

D. The '880 patent

On January 17, 2006, DBM filed a patent application, entitled “Closed-loop feedback-driven sympathetic neuromodulation for affect control,” that issued as the '880 patent. Dkt. No. 1-3 at 1. This application claimed priority to the '813 and '787 patents. *Id.* The claims in the application related exclusively to an invention within the Field of Use, under ¶ 6 of the Agreement, concerning sympathetic nervous system modulation therapy. *See, e.g.*, Dkt. No. 1-3 at claim 56 (“A system for *neural modulation of the sympathetic nervous system*”). The application’s internal docket number was “ANSTIM 01.02,” in which “ANSTIM” stood for “Autonomic Nervous System Stimulation.” DiLorenzo Decl. ¶ 7. Dr. DiLorenzo filed this

application himself, whereas other applications listing him as an inventor were filed by counsel for BioNeuronics. *Id.* DBM paid for the preparation and prosecution of this application and the maintenance of the '880 patent. *Id.* ¶ 8. BioNeuronics made no payment related to the '880 patent. *Id.*

Because the claims in the application pertained to DBM's Exclusive Field of Use, ownership thereof would be DBM's. *See* Agreement ¶ 6. As such, per the Agreement, DBM would be responsible for costs of filing and prosecuting the patents and subsequent patent maintenance, and in fact DBM carried those payments. DiLorenzo Decl. ¶ 8.

Dr. DiLorenzo duly gave John Harris, CEO of BioNeuronics, written notice of the application that issued as the '880 patent, along with several other of his applications, on or around April 21, 2006. *Id.* ¶ 10. Dr. DiLorenzo expressed the position that the applications disclosed therein were owned by DBM pursuant to ¶ 6 of the Agreement. *Id.* Dr. DiLorenzo further asked Mr. Harris to confirm that these applications were properly within DBM's ownership. *Id.*

In a letter dated May 25, 2006, Mr. Harris responded to Dr. DiLorenzo's written notice. DiLorenzo Decl., Ex. 4. Mr. Harris stated therein that BioNeuronics was "[REDACTED]

[REDACTED]" DiLorenzo Decl., Ex. 4 at 1. However, because the applications were still pending, Mr. Harris expressed that they would defer determining "[REDACTED]

[REDACTED]" until the patents issued. DiLorenzo Decl., Ex. 4 at 2. Mr. Harris stated, "[REDACTED]

[REDACTED]" *Id.* At no time after this letter did

BioNeuronics (or any of its successors-in-interest) contact Dr. DiLorenzo to transfer or change record ownership of the '880 patent. Nor can he recall any instance, at any time prior to LivaNova's responding to this lawsuit (seven years after the '880 patent issued), in which LivaNova or its predecessors brought to his attention any suggestion that this should be done. *Id.*

LEGAL STANDARDS

A. Motion to dismiss

A Rule 12(b)(1) motion may be based on: (1) the complaint alone; (2) the complaint supplemented by undisputed facts of record; or (3) the complaint supplemented by undisputed facts and the court's resolution of disputed facts. *Clark v. Tarrant County, Texas*, 798 F.2d 736, 741 (5th Cir. 1986). However, the Court need not look beyond the complaint or resolve disputed facts unless it chooses to do so.⁷

Where the jurisdictional facts are intertwined with the merits, such as where “where the statute provides both the basis of federal court subject matter jurisdiction and the cause of action” (*id.* at 742), “the case should not be dismissed for lack of subject matter jurisdiction unless the alleged claim is immaterial or is wholly insubstantial and frivolous.” *Id.* at 741–42. Moreover, in this case, LivaNova has not authenticated any of its exhibits, raising a question as to whether the Court should even consider them.⁸

B. Standing requirements for patent infringement claims

The requirements for an exclusive patent licensee to bring a suit for infringement were

⁷ LivaNova also moves under Rule 12(b)(7). LivaNova's only argument as to this ground is that it follows from its assertions regarding Rule 12(b)(1) that DBM has also failed to join an indispensable party under Rule 12(b)(7).

⁸ See, e.g., *Wilhite v. Reg'l Employers' Assurance Leagues VEBA Tr.*, No. CV B-11-059, 2011 WL 13254064, at *4–5 (S.D. Tex. Nov. 15, 2011) (Hanen, J.) (denying motion to dismiss based in part on Rule 12(b)(1) where movant relied on documents that had “not been authenticated or proven up”).

broadly set out by the Supreme Court in *Waterman v. Mackenzie*, 138 U.S. 252 (1891), addressed in detail below. *Waterman* holds that an exclusive licensee of less than the entire interest in a patent must ordinarily join the patentee as a co-plaintiff—but that an exception exists where (as here) it is the patentee itself that is accused of infringement. 138 U.S. at 255.

ARGUMENT

A. DBM does not need to join LivaNova as a party in order to sue it for infringement within the Field of Use.

Under a long-held exception recognized in *Waterman*, an exclusive licensee that does not have all substantial rights *does* have standing to sue in its own name when “necessary to prevent an absolute failure of justice, as where the patentee is the infringer, and cannot sue himself.”

Waterman, 138 U.S. at 255. The present case falls squarely within this exception.

1. DBM holds an exclusive license to the '813 and '787 patents within the Field of Use.

Paragraph 4 of the Agreement expressly conveys to DBM exclusive rights with respect to the '813 and '787 patents in the specified Field of Use. LivaNova points to the mere fact that the licensed Field of Use covers less than the entire interest, which is clearly acknowledged in the Complaint. Notably, however, LivaNova does *not* dispute that the grant nevertheless constitutes as “exclusive” license within the specified field.

2. An exclusive licensee has prudential standing to bring suit against the patentee.

LivaNova argues “a substantial risk of multiple suits and multiple liabilities against an alleged infringer for a single act of infringement” (Mot. at 10–11, citing *Alps S., LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1383–84 (Fed. Cir. 2015)), which goes to what is referred to as “prudential standing.” The entire answer to this contention is that, unlike the defendant in *Alps*, which was a third-party infringer, LivaNova is the patent owner and is already in this case as a defendant, and as such can adequately represent its own interests herein.

In a more recent case, a court faced an argument similar to that made by LivaNova (*see* Mot. at 11–12) that the exclusive licensee lacked “substantial rights” and thus lacked standing without joining the patent owner. *Diamondback Indus., Inc. v. Repeat Precision, LLC*, No. 6:19-CV-00034-ADA, 2019 WL 8501017, at *4 (W.D. Tex. Sept. 11, 2019). The court noted both the general rule and exception articulated above and found that the case fell “squarely into that exception [because] the exclusive licensee in this case ... is suing the patentee ... for infringement of the [licensed] Patent, which is exactly the situation covered by the exception to the prudential standing requirement.” *Id.*

LivaNova’s argument that DBM is “merely a licensee in a Field of Use” (*see, e.g.*, Mot. at 2, 9) and thus was required to join LivaNova is unavailing because LivaNova is not a third party but rather the patentee and is already the defendant in this case. For example, in the *Alps* case, the Federal Circuit held that “our standing jurisprudence required that [plaintiff] Alps join the patent owner, AEI, as a co-plaintiff” in order to have standing to sue defendant and third party Ohio Willow Wood. *Alps S., LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1386 (Fed. Cir. 2015). In so holding, the court cited reasoning from its own precedent that “finding that a field of use licensee has standing to sue in its own name alone poses a substantial risk of multiple suits and multiple liabilities against an alleged infringer for a single act of infringement.” *Id.* at 1384 (internal quotations and citations omitted). Here, this rationale does not apply. Because the “alleged infringer” in this case is LivaNova, the patent owner, there is no “substantial risk of multiple suits and multiple liabilities.”

Remarkably, the Motion (at 12) actually *references* the well-established exception stated in *Waterman* but seeks to avoid it with a supposed *further* requirement that in addition to providing exclusive rights, the license grant itself must expressly recite a right to sue. LivaNova

points to no authority for such a further requirement, and no such further requirement exists. *See Alnylam Pharms., Inc. v. Tekmira Pharms. Corp.*, No. 12-10087-RWZ, 2012 WL 4857580, at *2 (D. Mass. Sept. 24, 2012) (finding explicit grant to an exclusive licensee within a field of use the right to sue third parties did not implicitly deny it the right to sue the patent owner). LivaNova also relies on ¶ 10 of the Agreement, which concerns infringements by third parties but is irrelevant because LivaNova is not a third party.

B. DBM's Field of Use is not limited to treating obesity and other metabolic disorders.

1. The plain grammatical reading of the Field of Use demonstrates the grant of two separate branches.

LivaNova bases most of its motion on the interpretation that Plaintiff's exclusive Field of Use is limited to obesity and metabolic disorders. This is simply fallacious. From a grammatical perspective, the Field of Use separately recites two distinct branches:

devices and methods *for* sympathetic nervous system modulation therapy and
for neuromodulation therapy for treating obesity and other metabolic disorders

Agreement ¶ 4 (emphasis added). “For” is used in the Field of Use “as a function word to indicate purpose.”⁹ The Field of Use recites a first purpose for the recited “devices and methods,” followed by a second and distinct purpose, both introduced with a “for” and separated by an “and.”

LivaNova argues that the phrase “for treating obesity and other metabolic disorders” modifies *both* “sympathetic nervous system modulation therapy” *and* “neuromodulation therapy.” *See, e.g.*, Mot. at 13. However, such an interpretation violates the last antecedent rule applied in Washington, which instructs that “qualifying word and phrases refer to the last

⁹ *See For Definition & Meaning*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/for> (Abramson Decl., Ex. 3).

antecedent.” *See, e.g., In re Sehome Park Care Ctr., Inc.*, 903 P.2d 443, 447 (Wash. 1995). If the parties to the Agreement had indeed intended the qualifying phrase “for treating obesity and other metabolic disorders” to apply to **both** “sympathetic nervous system modulation therapy” **and** “neuromodulation therapy,” they would have inserted a comma before said qualifying phrase (*i.e.*, an inserted comma before “for treating obesity ...”). *See id.* (“[T]he presence of a comma before the qualifying phrase is evidence the qualifier is intended to apply to all antecedents instead of only the immediately preceding one.” (citation omitted)).

2. LivaNova’s interpretation of the Field of Use would give no effect to the words “sympathetic nervous system modulation therapy.”

Washington courts require “giv[ing] lawful effect to all the provisions in a contract,” rather than “render[ing] some of the language meaningless or ineffective.” *Grey v. Leach*, 244 P.3d 970, 976 (Wash. Ct. App. 2010). LivaNova’s interpretation of the Field of Use would render the words “sympathetic nervous system modulation therapy” therein ineffective.

As described above, neuromodulation generally means any stimulation of the nervous system. *See supra* p. 4. The nervous system includes the peripheral nervous system, which includes the autonomic nervous system, which in turn includes the sympathetic nervous system. *Id.* Thus, just as the sympathetic nervous system is subsumed by the nervous system, “sympathetic nervous system modulation therapy” is entirely subsumed by “neuromodulation therapy.”

LivaNova’s interpretation is that **both** “sympathetic nervous system modulation therapy” **and** “neuromodulation therapy” are limited by the words “for treating obesity and other metabolic disorders.” However, because “sympathetic nervous system modulation therapy” is a subset of “neuromodulation therapy” and wholly subsumed thereby, the words “sympathetic nervous system modulation therapy” would add nothing to what the grant would cover without

those words. LivaNova's interpretation would thus render those ineffective. Such a reading is contrary to Washington canons of contract interpretation and thus should be rejected.

C. LivaNova fails to note the limitations of the “context rule.”

LivaNova invokes the “context rule” under Washington law (Mot. at 13), citing *Microsoft Corp. v. Motorola, Inc.*, 864 F. Supp. 2d 1023 (W.D. Wash. 2012), which in turn relied on *Berg v. Hudesman*, 801 P.2d 222 (Wash. 1990). The Court should be aware, however, that in 2005, the Supreme Court of Washington, sitting *en banc*, addressed “confusion over the implications of *Berg* [and the context rule].” *Hearst Communications, Inc. v. Seattle Times Co.*, 15 P.3d 262, 266 (Wash. 2005) (*en banc*). Some courts in Washington had initially viewed *Berg* as “authorizing unrestricted use of extrinsic evidence in contract analysis.” *Id.* Rather, the *Hearst* court clarified that “surrounding circumstances and other extrinsic evidence are to be used to determine the meaning of *specific words and terms used* and not to show an intention independent of the instrument or to vary, contradict or modify the written word.” *Id.* at 267 (emphasis in original) (internal quotations and citation omitted).

Acknowledging that “[its] holding in *Berg* may have been misunderstood as it implicates the admission of parol and extrinsic evidence,” the *Hearst* court stated:

We take this opportunity to acknowledge that Washington continues to follow the objective manifestation theory of contracts. Under this approach, we attempt to determine the parties’ intent by ***focusing on the objective manifestations of the agreement***, rather than on the unexpressed subjective intent of the parties.

Id. (emphasis added) (citation omitted). “Thus, when interpreting contracts, the subjective intent of the parties is generally irrelevant if the intent can be determined from the actual words used.” *Hearst*, 115 P.3d at 267. Washington courts must also “giv[e] lawful effect to all the provisions in a contract,” rather than “render[ing] some of the language meaningless or ineffective.” *Grey*, 244 P.3d at 976. “***We do not interpret what was intended to be written but what was written.***”

Hearst, 115 P.3d at 267 (emphasis added).

1. Determining intent must proceed from what was written.

a) *Subject matter and objective of the agreement*

The first factor of the context rule under *Berg* and *Hearst* concerns “the subject matter and objective of the contract.” No one can dispute that the subject matter was of course a grant back of some of the rights that Dr. DiLorenzo had transferred to NeuroBionics months earlier. With regard to “objective,” LivaNova proposes the wrong approach, focusing on how it now characterizes the alleged future needs of NeuroBionics’ business,¹⁰ rather than what the Agreement expressly recites. As to the latter, the recital (at page 2 of the Agreement) lays out only what an *earlier agreement* said (the Ex. C Assignment, dated December 14, 2004), which was that “By January 31, 2005, or as soon as practicable thereafter, the Company and the undersigned [Dr. DiLorenzo] will use their best efforts” to negotiate a license back of the assigned IP, which broadly related to “neurodiagnostics and neuromodulation” generally. The 2004 Assignment (Ex. C) contemplated that this negotiation would relate to a license back for “obesity and metabolism”—words that LivaNova now seizes upon as controlling for all time. However, akin to a letter of intent, the LOI does not control the scope of the final agreement actually reached, certainly not to the point of changing how one would construe the final agreed written terms, where ordinary rules of construction render the final terms unambiguous.

LivaNova’s brief also fails to mention that the Agreement contains an integration clause (§ 17), stating that it (and not any earlier agreement) represents the “final” agreement on the subject matter. Washington courts have cautioned that, where a contract contains an integration

¹⁰ See Mot. at 17 (“[T]he intent of those agreements was to divide the rights in the Asserted Patents between epilepsy treatment and the treatment of obesity and metabolic disorders.”).

clause, extrinsic evidence may only be used “to explain undefined contract terms, not to modify, vary, or contradict terms of the written contract.” *King v. Rice*, 191 P.3d 946, 951 (Wash. Ct. App. 2008) (emphasis added).

LivaNova’s arguments regarding Exs. A–D (Mot. at 15) largely relate to Dr. DiLorenzo’s obligation to assign the ’813 and ’787 patents to BioNeuronics. There is no question that Dr. DiLorenzo did so. LivaNova’s remaining argument regarding certain inventions Dr. DiLorenzo “carve[d] out” relating to “Autonomic Modulation and Neuromodulation for Obesity & Metabolism” (*id.*) only serves as another example of LivaNova’s revisionism. LivaNova’s selective emphasis on the phrase “Obesity & Metabolism” again ignores that autonomic modulation is a subset of neuromodulation. *See supra* at p. 4. Therefore “Obesity & Metabolism” cannot modify both “Autonomic Modulation” and “Neuromodulation” without rendering the former without effect.

b) *Circumstances surrounding the making of the contract*

Dr. DiLorenzo’s accompanying declaration addresses the ***actual relevant context*** of the disputed license grant, which is that it arose in the wake of [REDACTED] in December 2004. That deal left the parties with a mutually acknowledged gap in their agreements reached at the time, as to the grant-back of patent rights, which was left to “best efforts” to reach a future agreement. This mere expression of intent to negotiate a future agreement did not dictate the terms of the future agreement itself, reached five months later. The provisions memorializing the parties’ intent to negotiate cannot be used to override the terms of the written agreement that was ultimately reached as a result of the negotiation. And negotiate they did, as reflected in the series of drafts reviewed above. The revisions reflected in the drafts leave no doubt that “sympathetic nervous system modulation therapy” was specifically intended to be a distinct part of the license grant. The parties were free to negotiate in good faith, and

where that negotiation landed is best understood by the words they finally agreed to as a result, as made even more clear in this case by the course of drafting.

c) Subsequent acts and conduct of the parties

LivaNova again turns to extrinsic documents. Washington law allows such consultation within the limitations of *Hearst*. But the extrinsic documents that LivaNova cites do not at all support its position, and furthermore, there are additional documents that LivaNova fails to mention, which are flatly inconsistent with its position.

LivaNova raises Sec. 7.3 of the Separation Agreement (Ex. F). That provision, however, does **not** in fact address the scope of the exclusive license grant under Sec. 4 of the Agreement (Ex. E). Rather, it addresses the scope of a **different** license, a license from Dr. DiLorenzo to NeuroBionics in connection with the Inventions Agreement (Ex. D), as to which the parties agreed (in the Separation Agreement) to **import** terms used in Sec. 4 of the Agreement to govern the exclusive license under that provision **to** Dr. DiLorenzo. The language from Ex. F that LivaNova relies on serves merely to **identify** the un-numbered clause within Sec. 4 of Ex. E to be used as the source for the terms to be imported, **not to define or redefine** the substance of the source clause itself (and indeed so as to *avoid* doing so). The mere words chosen only **to identify** provisions to be adapted from a different agreement cannot be taken as defining the substantive scope of the full clause to be imported.

LivaNova also argues NeuroBionics’ “actual or projected line of business activity” recited in Ex. F (Mot. at 16), again as to a different agreement (Ex. D), but Dr. DiLorenzo had **already assigned** the ’813 and ’787 patents to NeuroBionics.

LivaNova quotes from a March 13, 2013 email, in which Dr. DiLorenzo states that “the

ownership of ¹¹ the IP is divided along fields of use, mine being metabolism and autonomic structures (amygdala, hypothalamus, etc.) and NeuroVista [a new corporate name for BioNeuronics]/Cyberonics [sic] being in epilepsy and other areas.” Ex. J at 2. Yet again, LivaNova glosses over “autonomic structures,” which plainly reference Dr. DiLorenzo’s ownership of his inventions in “Autonomic Modulation and Neuromodulation for Obesity & Metabolism.” *See, e.g.*, Ex. A, Schedule III, Appendix.

LivaNova then turns to correspondence (Exs. K–N) about ways to commercialize Dr. DiLorenzo’s inventions, including by pursuing patent infringement litigations against a third-party infringer “in the field of epilepsy treatment.” Mot. at 17–18. LivaNova argues that “Dr. DiLorenzo *knew* that he did not have rights in the patents relating to the field of epilepsy treatment.” *Id.* at 18 (emphasis in original). But no one has asserted that Dr. DiLorenzo’s exclusive rights cover any and all epilepsy treatment. Rather, DBM’s exclusive rights in the ’813 and ’787 patents extend to sympathetic nervous system modulation therapy, whether used to treat epilepsy or otherwise.

Additionally, Dr. DiLorenzo’s correspondence with Cyberonics demonstrates that Cyberonics understood that DBM’s Field of Use was not limited to treating obesity and other metabolic disorders. On August 21, 2013, Dr. DiLorenzo emailed David Wise, who LivaNova identified as “the then-General Counsel of Cyberonics” regarding [REDACTED] [REDACTED] Ex. K at 9–12; Mot. at 7. In response, Mr. Wise asked whether Dr. DiLorenzo was “referring to [REDACTED] that pertain to the obesity / metabolic disorder indication.” Ex. K at 9. Dr. DiLorenzo responded, “[REDACTED]

¹¹ LivaNova’s quotation (Mot. at 17) omits this these three words addressing “ownership,” trying to represent the email as addressing the scope of a license.

_____.” *Id.* (emphasis added). Rather than correcting Dr. DiLorenzo that autonomic modulation (in particular, sympathetic modulation) was not within Dr. DiLorenzo’s Field of Use, Mr. Wise agreed that it, together with the “_____,” made up the Field of Use (*id.* at 8):

Exs. M and N, relating to Dr. DiLorenzo's [REDACTED]
[REDACTED], reflects nothing more than the fact that LivaNova would not agree to join as a plaintiff in an infringement suit against a third party.¹²

LivaNova argues that “Dr. DiLorenzo’s silence relating to any alleged infringement by LivaNova” shows he did not believe he had rights “outside the field of treating obesity and metabolic disorders.” Mot. at 18–19. Dr. DiLorenzo repeatedly stated that his rights were ***not*** so limited, *e.g.*, directly claiming ownership in the ’880 patent, overtly claiming sympathetic nervous system modulation therapy (DiLorenzo Decl. ¶ 10); Ex. J at 2 (“[REDACTED] [REDACTED]”) (emphasis added)); Ex. K at 8 (Dr. DiLorenzo’s Field of Use included “[REDACTED],” not just “[REDACTED]”). DBM had not pursued a claim of patent infringement against LivaNova until now because it had hoped to find

¹² In its Motion, LivaNova references the statement in the draft Option Agreement that “[LivaNova] has not itself ever made, offered for sale, or sold any patented articles covered by the [patents] in the United States, nor imported any patented article covered by the [patents] into the United States.” Mot. at 8 (quoting Ex. N ¶ 4(c)). This representation does not reflect DBM’s subsequent allegations of infringement against LivaNova. In any event, the option agreement was not executed by either party.

a way to collaborate with LivaNova, as well documented in LivaNova's exhibits.

d) Reasonableness of respective interpretations urged by the parties

As addressed *supra* at pp. 12–13, DBM's interpretation aligns with an interpretation in accordance with ordinary rules of grammar, whereas LivaNova's interpretation fails to give effect to the words “sympathetic nervous system modulation therapy.”¹³

D. DBM owns the '880 patent.

As described *supra* at pp. 7–9, pursuant to ¶ 6 of the Agreement, DBM is the owner of the '880 patent. It claims priority to the Licensed Patents, and all of its claims are for “sympathetic nervous system modulation therapy” and within the Field of Use. DBM's ownership is further evidenced by its payment for the prosecution and the maintenance.

DBM did what the parties' agreements required and duly notified LivaNova's predecessor-in-interest in writing of the filing of the '880 patent. DiLorenzo Decl. ¶ 7. DBM, and not BioNeuronics, paid for the preparation and prosecution of the application and the maintenance of the '880 patent. *Id.* ¶¶ 7–8. As expressed above, while it initially expressed “concerns” about the scope of some of Dr. DiLorenzo's pending claims, BioNeuronics has never contacted DBM to transfer or change record ownership of the '880 patent, or, at any time prior to responding to this lawsuit in 2023, express that this should be done. *Id.* ¶ 11. The '880 patent belongs to DBM. This Court cannot rule otherwise on a motion to dismiss, certainly not on the present record.

CONCLUSION

For the foregoing reasons, LivaNova's Motion should be denied.

¹³ LivaNova did not address the remaining “context” factors identified in Washington decisions.

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Respectfully submitted,

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